EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION v. This Document Relates To: All cases referenced in MDL Dkt. Nos. 1471, 1472 and Lambert, 1:13-cv-10351, Dkt Nos. 29, 30.	MDL No. 2419 Master Docket: 1:13-md-2419-RWZ

LIBERTY INDUSTRIES, INC.'S REPLY IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

Liberty Industries, Inc. ("Liberty") files this Reply to the Plaintiffs' Steering Committee's ("PSC") Opposition to Liberty's Omnibus Motion for Summary Judgment in Cases Filed by Plaintiffs Injected in Indiana. Liberty's motions for summary judgment seek summary judgment in favor of Liberty because there is no evidence to support the claims asserted against it in this matter. The PSC's Opposition comes after this Court denied its Rule 56(d) motion. In its Rule 56(d) motion, the PSC claimed that certain additional evidence was essential to its claims against Liberty. Because the PSC's Opposition sets forth no admissible evidence essential to raise a genuine issue of material fact, summary judgment in favor of Liberty must enter.

II. SUMMARY JUDGMENT STANDARD

Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A party may show that a fact cannot be genuinely disputed by either citing to material in the record or showing that "an adverse party cannot produce admissible evidence to support the fact." Id. at 56(c). The First Circuit has explained the summary judgment burden of a non-moving party as follows:

> 'The very mission of the summary judgment procedure is to pierce the pleadings and assess the proof in order to see whether there is a genuine need for a trial.'…In assessing this proof, Rule 56[(c)] charges the district court with ensuring that the evidence proffered in opposition to a motion for summary judgment has foundation sufficient to allow it to reach a jury. If the nonmoving party is unable to provide such admissible proof, then the court is unable to say that there exists a 'genuine need for trial.' Schubert v. Nissan Motor Corp. in U.S.A., 148 F.3d 25, 32 (1st Cir. 1998), quoting DeNovellis v. Shalala, 124 F.3d 298, 305-06 (1st Cir. 1997).

The PSC has failed to produce any admissible evidence establishing "a genuine need for trial" against Liberty. Liberty is entitled to summary judgment in its favor.

III. LEGAL ARGUMENT

In its Rule 56(d) motion, the PSC claimed that it needed to conduct discovery to "provide evidence necessary to support elements of the PSC's claims such as duty and breach" and "for purposes of establishing causation." See PSC's Supplemental Response to Liberty's Omnibus Motion for Summary Judgment ("Rule 56(d) motion") [Dkt. No. 1593]. Its motion was denied [Dkt. No. 1601]. The PSC admitted, before filing its Opposition, it did not have evidence necessary to support its claims against Liberty. It fares no better now.

The PSC said it needed depositions of the owner of Liberty and certain former Liberty employees regarding "design of the 2005 cleanroom," "addition of the passthrough to the 2006 cleanroom," and "the decision not to add a secondary ceiling to the 2006 cleanroom." See Rule 56(d) motion, p. 2. The PSC also said it needed discovery from NECC confirming "that the contaminated MPA was compounded in the 2006 cleanroom designed and built by Liberty," "Liberty's representations to NECC about intended use of its cleanrooms," and "whether NECC significantly modified the Liberty built cleanrooms." Id. In addition, the PSC claimed "[e]xperts will be needed…especially for purposes of establishing causation." Id., p. 9. Its untimely Opposition [Dkt. No.1610] was supported by a Declaration of a supposed expert [Dkt. No. 1610-1] that is neither sworn to, nor made under the pains and penalties of perjury. The PSC did not fill the gaps that the PSC admitted existed in its case.[1]

[1] According to the Court's Order dated December 17, 2014 [Dkt. No. 1601], the PSC's Opposition to Liberty's motions for summary judgment was due December 22, 2014. In order to be considered timely filed, the PSC's Opposition had to be filed prior to 6:00 p.m. on December 22, 2014. See Local Rule 5.4(D) ("Although the ECF system is generally available 24 hours a day for electronic filing, that availability will not alter filing deadlines, whether set by rule, court order, or stipulation. All electronic transmissions of documents must be completed prior to 6:00 p.m. to be considered timely filed that day.") In direct violation of Local Rule 5.4 and this Court's Order, the PSC waited until 11:58 p.m. to file its Opposition. The Opposition is untimely, and Liberty's motions for summary judgment should be allowed for this reason alone. Additionally, Liberty intends to file a motion to strike the PSC's Opposition due to its untimeliness.

A. The PSC Has Failed to Set Forth the Evidence The PSC Deemed Essential to Its Claims.

1. The PSC Has Not Presented Necessary, Admissible Expert Testimony.

The PSC claimed that "[e]xperts will be needed as fact discovery progresses especially for purposes of establishing causation." See Rule 56(d) motion, p. 9. Despite this admission, the PSC's Opposition, as discussed below, is devoid of any admissible expert opinion creating a genuine issue of material fact as to causation. The PSC's alleged expert, Dr. Philip J. Austin ("Dr. Austin, Jr."), states:

> As with any biological contamination event, such as that which occurred with the contaminated vials of MPA at NECC, there are a number of possible causes. Sufficient evidence exists to conclude that the fungal contamination occurred during some aspect of the compounding process at NECC. Due to the number of possible causes for contamination during the compounding process, it is unlikely that any definitive path of fungal contamination from an originating source to its final destination in the vials will be able to be identified. At best, only after a thorough investigation process, likely contamination paths can be identified and assigned various levels of probability.

Declaration of Dr. Philip J. Austin, Ph. D [Dkt. No. 1610-1] ("Declaration"), ¶51 [emphasis added]. Having admitted that the essential element of the PSC's claims, causation, cannot be proven, Dr. Austin, Jr.'s Declaration cannot support the PSC's claims against Liberty. If anything, the Declaration supports the grant of summary judgment in favor of Liberty. It exposes the fatal hole in the PSC's case, its inability to prove causation. The PSC has failed to carry its burden as the non-moving party with the burden of proof.

2. The PSC Has Not, Cannot and Will Not Present Any Evidence From NECC Witnesses

The PSC admitted that it needs evidence concerning operation of the cleanrooms. See Rule 56(d) motion, pp. 2, 7-9. Last week, fourteen NECC officers, directors, shareholders, former employees, and NECC affiliated persons were indicted by a Grand Jury in this Court.

See Exhibit A-1, U.S. v. Cadden, et al., 1:14-cr-10363-RGS [Dkt. No. 1] ("Indictment"). The charges include sweeping allegations of conspiracy in connection with the operation of the cleanrooms at NECC. Id. The PSC has claimed it needed testimony from these or other persons affiliated with NECC. See Rule 56(d) motion, p. 2. No affidavits from these persons have been served. None will be forthcoming.

This gap is fatal to the claims asserted against Liberty. As an example, the PSC has not presented admissible evidence concerning where the MPA involved in the outbreak of fungal meningitis was compounded. The conclusory statements of Dr. Austin, Jr. are devoid of any supporting facts and are inadmissible. His statements that "our observations lead us to the conclusion that the contaminated MPA was most likely compounded in the main area of the 2006 cleanroom" and "[i]nformation obtained since that time also appears to support the conclusion" (see Declaration, ¶34), even if considered his opinion and not his father's, are inadmissible.[2] They contain no statement of what was observed to substantiate them.

3. The PSC Has Produce No Admissible Evidence Liberty Caused the Outbreak.

The PSC must prove not only a breach of duty by Liberty, but also that such breach was the proximate cause of the plaintiffs' injuries. See Kincade v. MAC Corp., 773 N.E. 2d 909, 911 (Ind. Ct. App. 2002). The PSC has not presented admissible evidence on the causation element of its claims. The PSC conceded that "[e]xperts will be needed...for purposes of establishing causation." See Rule 56(d) motion, p. 9.

The purported expert Declaration of Dr. Austin, Jr. is deficient in the following respects:

1. The Declaration does not meet the requirements of Rule 56(c)(4) because it is not sworn or stated to be under the pains and penalties of perjury. 28 U.S.C. § 1746;

[2] See infra Section A.3, in which Dr. Austin, Jr.'s repeated references, in connection with his father, Dr. Philip R. Austin, to "we" and "our observations" are discussed in greater detail.

2. Dr. Austin, Jr. seeks to piggyback his father's expertise. It cannot be determined what Dr. Austin, Jr., as opposed to his father, observed or concluded;
3. The Declaration does not meet the requirements of Rule 56(c)(4) because Dr. Austin, Jr. has no personal knowledge of the conditions of the cleanrooms at any time before December, 2012;
4. Dr. Austin, Jr.'s speculation about the room in which the MPA was compounded is inadmissible without a statement of the facts supporting his speculation;
5. Dr. Austin, Jr. states that Liberty knew the cleanrooms were to be used for sterile compounding without any basis in fact for that statement; and
6. Dr. Austin, Jr. admits that the cause of the outbreak cannot be identified, undermining any reliance by the PSC on his Declaration to establish causation in this matter.[3]

With respect to item (1), 28 U.S.C. § 1746 mandates that unsworn declarations filed in opposition to motions be subscribed under the penalty of perjury. 28 U.S.C. § 1746. Because the Declaration is neither sworn, nor stated to be made under the penalty of perjury, it is inadmissible and should be excluded by the Court.

With respect to item (2), Dr. Austin, Jr. makes repeated reference to "we" and "our observations" in reference to his father, Dr. Philip R. Austin, who has not submitted a declaration, in an attempt to piggyback on his father's expertise. These references include:

- "In preparation of this declaration, I have considered the observations made by Dr. Philip R. Austin and me…" Declaration, ¶3 [emphasis added].
- "In December of 2012, my father, Dr. Philip R. Austin, and I were retained as consultants with expertise in the area of cleanroom design and contamination control." Id. at ¶33.

[3] Liberty also intends to file a motion to strike the Declaration based on each of these deficiencies.

- "During our investigation, our observations led us to the conclusion that the contaminated MPA was most likely compounded in the main area of the 2006 cleanroom…" Id. at ¶34 [emphasis added].

- "During our inspection of the cleanroom in December of 2012, we identified several defects in the design and construction of the NECC cleanrooms. In particular, it was our conclusion that the most probable vector for the contamination was directly related to a defect in the design and construction of the main area of the 2006 cleanroom. Although we have been provided with additional information since our initial investigation, we still believe that the defects in the design and construction of the NECC cleanrooms played a key role in the contamination of vials of MPA." Id. at ¶35 [emphasis added].

It cannot be determined what Dr. Austin, Jr., as opposed to his father, observed or concluded, rendering the Declaration without a proper foundation and inadmissible. Dr. Austin, Jr. cannot incorporate his father's purported observations and opinions as his own.

With respect to items (3), (4), and (5), the Declaration does not meet the requirements of Fed.R.Civ.P. 56(c)(4) because it makes conclusory and speculative statements against Liberty as to which Dr. Austin, Jr. has no personal knowledge. Fed.R.Civ.P. 56(c)(4) requires that a declaration used to oppose a motion "be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." The Declaration is based entirely on observations, photos, and tests taken during "the three day inspection of NECC in December, 2012." See Declaration, ¶3. Dr. Austin, Jr. does not have personal knowledge of the conditions of the cleanrooms at the time that Liberty delivered the cleanrooms to NECC and/or Ameridose or the time that the contaminated MPA was compounded. In the absence of such personal knowledge or other admissible evidence upon which to base his testimony, Dr. Austin, Jr. can offer no admissible expert opinion regarding alleged defects in Liberty's design and construction of the cleanrooms. See Fed.R.Civ.P. 56(c)(4). Further, Dr. Austin, Jr.'s additional conclusory statements regarding the cleanroom in which the contaminated MPA was compounded, see e.g. Declaration, ¶¶34, 39, and Liberty's

purported knowledge that the cleanrooms were to be used for sterile compounding, see e.g. Declaration, ¶¶4, 53, are also inadmissible because Dr. Austin, Jr. provides no basis in fact for the conclusions. See Fed.R.Civ.P. 56(c)(4).

Finally, with respect to item (6), Dr. Austin, Jr admits that the cause of the outbreak cannot be identified, stating: "As with any biological contamination event, such as that which occurred with the contaminated vials of MPA at NECC, there are a number of possible causes…Due to the number of possible causes for contamination during the compounding process, it is unlikely that any definitive path of fungal contamination from an originating source to its final destination in the vials will be able to be identified." See Declaration, ¶51 [emphasis added]. Dr. Austin, Jr.'s statements undermine the very conclusion that the PSC seeks to prove, that Liberty caused the outbreak.

B. NECC's Breaches of Regulatory Duties Were An Intervening Act and Superseding Cause of the Fungal Meningitis Outbreak.

Even if the PSC could prove that Liberty was negligent, which it cannot, NECC's widespread poor (and criminal) practices in failing to fulfill its duties under applicable pharmaceutical regulations for the production of sterile drugs is a superseding cause that breaks any alleged causal connection between Liberty and the subject outbreak. A negligent defendant who "sets into motion a chain of events" will not be liable for an "ultimate injury [that] was not reasonably foreseeable as the natural and probable consequence of the act or omission." See Control Techniques, Inc. v. Johnson, 762 N.E.2d 104, 108 (Ind. 2002). A "superseding cause" is an event that is "not reasonably foreseeable" and it means the "original actor did not cause the harm and receives zero share of any liability." Id. at 109. "[W]here the injuries could not, as a matter of law, have been reasonably foreseeable due to the unforeseeability of an intervening, superseding cause, summary judgment may appropriately be entered in favor of the defendant."

Wolfe v. Stork RMS-Protecon, Inc. f/k/a Stork Protecon, Inc., 683 N.E.2d 264, 268 (Ind. Ct. App. 1997), citing Havert v. Caldwell, 452 N.E.2d 154, 159 (Ind. 1993).

The criminal indictment recently filed against NECC personnel identify the various regulatory obligations imposed under Chapter 797 of the United States Pharmacopeia ("USP 797") by way of Section 9.01(3) of Title 247 of the Code of Massachusetts Regulations. See Exhibit A-1. As set forth in the Indictment:

- "…USP-797…set forth the standards for compounding drugs identified as sterile. All compounding personnel were responsible for understanding the fundamental practices and procedures outlined in USP-797 for developing and implementing appropriate procedures, and for continually evaluating the procedures and quality of sterile drugs." Exhibit A-1, ¶19.

- "USP-797's standards were meant to prevent harm, including death, to patients that could result from non-sterility of drugs. Non-sterility of purportedly sterile drugs was especially dangerous to patients when the drugs would be administered into the patients' body cavities, central nervous system, vascular systems, eyes, and joints." Exhibit A-1, ¶20.

- "USP-797 mandated that all high-risk drugs prepared in groups of more than 25 individual single-dose packages or multiple-dose vials be tested for sterility consistent with the standards set forth in Chapter 71 of the USP ("USP-71"). In addition, USP-797 mandated that all high-risk drugs, regardless of quantity, with assigned BUDs beyond 24 hours at room temperature be sterility tested. USP-71 defined sterility as the absence of the growth of microorganisms over a 14-day period. USP-71 set forth the minimum number of articles (*i.e.*, vials, syringes, bags) from varying batch sizes that had to be sterility tested to meet USP requirements." Exhibit A-1, ¶24.

- "USP-797 allowed for dispensing of high-risk drugs to patients prior to the receipt of sterility test results if the patient and the physician were notified of the potential risk, and an immediate recall was instituted if microbial growth was observed during the test. Any positive sterility test result should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls to identify the sources of contamination and to correct problems in the methods or processes." Exhibit A-1, ¶25.

NECC personnel were charged with criminal breaches of each of these duties between May and August, 2012. Id. Had they complied with those duties, the result would have been the production of sterile uncontaminated MPA or, at the very least, discovery that the subject MPA

was contaminated and not fit for production prior to dispensing it. That is, if NECC personnel had fulfilled their duties under USP 797 and performed the appropriate sterility tests on the subject MPA prior to dispensing it, they would have discovered that the subject MPA was contaminated and dangerous to human health and would not have dispensed it. The subject outbreak simply would not have occurred had NECC personnel not committed the crimes for which they are charged. The wholesale criminal failure of NECC personnel, as licensed pharmacists charged with certain regulatory and legal obligations, to follow these basic health and safety standards was not and could not be reasonably foreseeable to Liberty, such that Liberty did not cause the subject outbreak and cannot be liable for it. See Control Techniques, Inc., 762 N.E.2d at 109. [4]

IV. CONCLUSION

It is now more than a year since the PSC first made its broad and far-reaching allegations against Liberty. Yet, when faced with Liberty's summary judgment motions, the PSC has been unable to provide any factual basis for those allegations. While it has asserted that certain evidence is essential to its claims against Liberty, it has failed to submit such evidence in its Opposition. In addition, the PSC's Opposition is completely devoid of any admissible expert testimony to prove the essential element of its claims, causation. The Declaration of the PSC's

[4] Alternatively, the proceedings against Liberty should, at the very least, be stayed pending the outcome of the criminal proceedings against NECC personnel related to the compounding of the MPA because proof of those allegations will, as a matter of law, dispose of the claims asserted against Liberty in this matter. This Court is vested with discretionary power to stay proceedings. Landis v. North Am. Co., 299 U.S. 248, 254-55 (1936). That power to stay "is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." Id. at 254. Further, "[a] stay is appropriate where it is 'likely to conserve judicial and party time, resources, and energy.'" Bank of America, N.A. v. WRT Realty, L.P., 769 F.Supp.2d 36, 39-40 (D. Mass. 2011), quoting Diomed, Inc. v. Total Vein Solutions, LLC, 498 F.Supp.2d 385, 387 (D. Mass. 2007). As set forth above, the Indictment alleges criminal breaches of duty on the part of NECC personnel in the compounding of the contaminated MPA. Those allegations, if proven, would, as a matter of law, break any alleged causal connection between Liberty and the plaintiffs' injuries, thereby obviating the need for any further litigation of the claims against Liberty. Accordingly, a stay of the proceedings against Liberty pending the outcome of those criminal allegations related to the compounding of the MPA would be the most efficient use of the time, resources, and energy of the Court and the parties, and would, therefore, be appropriate.

purported expert actually admits that the cause of the outbreak cannot be identified. In sum, the PSC has made serious allegations against Liberty in seeking to hold it liable for a tragic health crisis but has been unable to support those allegations with actual facts. As such, for the reasons stated herein and in Liberty's motions for summary judgment, summary judgment must enter in favor of Liberty.

WHEREFORE, Liberty respectfully requests that the Court grant summary judgment in favor of Liberty.

Respectfully submitted,

LIBERTY INDUSTRIES, INC.,
By its attorneys,

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Dated: December 24, 2014

CERTIFICATE OF SERVICE

Pursuant to Local Rules 5.2(b)(2) and 5.4 of the Local Rules of the United States District Court for the District of Massachusetts, I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and that paper copies will be sent by first-class mail to those indicated as non-registered participants, if any, on December 24, 2014.

/s/ Peter G. Hermes
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